

## PATENT COOPERATION TREATY

PCT

## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

HUNTSMAN, Peter  
 Davies Collison Cave  
 1 Little Collins Street  
 Melbourne, VIC 3000  
 AUSTRALIE

TUESDAY, - 2 JAN 2001

<b>Date of mailing (day/month/year)</b> 21 December 2000 (21.12.00)			
<b>Applicant's or agent's file reference</b> 2301450/PHH		<b>IMPORTANT NOTICE</b>	
<b>International application No.</b> PCT/AU00/00652	<b>International filing date (day/month/year)</b> 09 June 2000 (09.06.00)	<b>Priority date (day/month/year)</b> 10 June 1999 (10.06.99)	
<b>Applicant</b> N & V CURIE PTY LTD et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AG,AU,DZ,KP,KR,MZ,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,  
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The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 21 December 2000 (21.12.00) under No. WO 00/76408

**REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)**

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

**REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))**

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b>  J. Zahra
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

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(71) Applicant (*for all designated States except US*): N & V  
CURIE PTY LTD [AU/AU]; 32 Cliff Road, Frankston,  
VIC 3199 (AU).

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): CURIE, Napoleon  
[AU/AU]; 32 Cliff Road, Frankston, VIC 3199 (AU).

(74) Agents: HUNTSMAN, Peter et al.; Davies Collison Cave,  
1 Little Collins Street, Melbourne, VIC 3000 (AU).

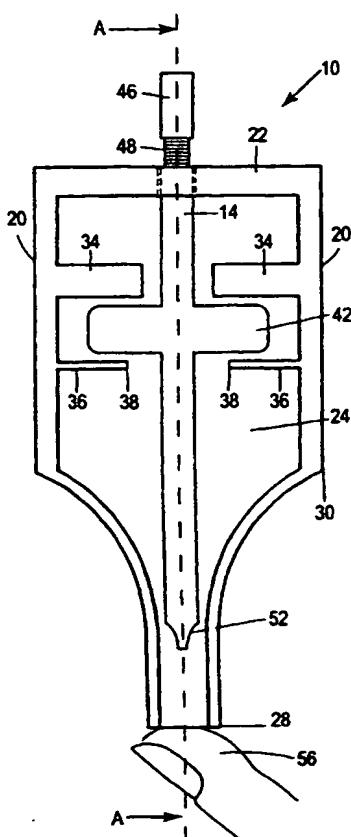
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*[Continued on next page]*

(54) Title: DISPOSABLE LANCET DEVICE



(57) Abstract: This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. It comprises a lancet housing (12), a lancet body (14) displaceably supported by the housing (12) and having a piercing tip (52) which is concealed within the housing (12) in a rest position of the body (14). It also comprises operating means (46) for manually displacing the lancet body (14) to expose the piercing tip (52). It includes biasing means (36) against which the lancet body (14) operates as it is manually displaced to expose the piercing tip (52), whereby the biasing means (36) automatically retracts the lancet body (14) to its rest position when the manual displacement force is removed from the operating means (46). Disabling the operating means (46) prevents manual displacement of the lancet body (14) from its rest position.

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10/09946  
JPO Rec'd PCT/PTO 10 DEC 2001

## DISPOSABLE LANCET DEVICE

This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. In particular, it relates to a 5 disposable lancet device of a relatively simple construction which can be used several times by a single user, but also has a disabling feature which can prevent reuse.

Lancet devices are currently available which enable a small quantity of blood to be let from an incision in human skin. Some diseases necessitate the testing of blood at regular 10 intervals. For instance, diabetes requires testing for glucose content of blood and this may be performed on a day to day basis by many patients. As such, lancet devices which pierce the skin to let an adequate amount of blood for testing are required for use by patients in the home and also for use by nurses or medical technicians who routinely conduct such tests on patients.

15 In cases where several patients are tested consecutively, there is often a risk of a spread of infection by the use of a single lancet device on more than one patient. Furthermore, in instances of home use the problem of erroneous results may arise if a lancet device which has previously been used is used again some time later and has retained remnants of old 20 blood which are subsequently included in the testing procedure. In order to counteract such problems devices which can only be used once have been proposed. Although these devices solve the problems addressed above they introduce a further problem in circumstances where a device fails to incise the skin on the first attempt, or if a device is accidentally activated, as a further attempt to incise the skin is not possible. Examples of 25 lancet devices which can only be used once are shown in US Patents 4,735,203 and 5,554,166. The inability to repeat a failed attempt at incising the skin and the necessity of using a second device introduces additional costs to the consumer.

The problem of risk of infection may also arise if the needle or piercing tip of the lancet 30 device is exposed and accidentally pricks a nurse or technician after the device has been used. Safety features enabling automatic retraction of the needle after piercing of the skin

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to prevent accidental cuts have also been proposed. However, these proposed devices involve complicated mechanisms which usually include a large number of components resulting in a device which is expensive to manufacture. Examples of proposed lancet devices of a complicated nature with a large number of components are given in US

- 5 Patents 5,554,166, mentioned above, and 5,741,288.

According to the present invention there is provided a disposable lancet device for piercing human skin comprising:

a lancet housing,

- 10 a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body,  
operating means for manually displacing the lancet body to expose the piercing tip, and  
biasing means against which the lancet body operates as it is manually displaced to expose  
the piercing tip whereby the biasing means automatically retracts the lancet body to its rest  
15 position when the manual displacement force is removed from the operating means,  
wherein disabling the operating means prevents manual displacement of the lancet body  
from its rest position.

The lancet device according to the present invention addresses the above problems in that  
20 it can be used several times by a single user, either in the home or by a person  
administering the incision, so that a first attempt can be repeated if it does not succeed.  
The device can also be disabled permanently to prevent reuse and has a concealed tip to  
alleviate accidental piercing of the skin. The device may also have a relatively simple  
construction. In particular, it avoids the use of complicated spring-loaded mechanisms in  
25 order to achieve successful incision of the skin.

The piercing tip is advantageously integral with the lancet body, and may be moulded with  
the lancet body in a plastics material such as polycarbonate, polystyrene or polypropylene.  
Polypropylene may not provide the tip with adequate piercing ability in which case  
30 polystyrene is preferred. In this embodiment, the tip is preferably formed of metal such as  
stainless steel. The tip may have a cylindrical body tapering to a pointed end, but

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preferably it is multi-sided, for example, pyramidal or flat with sharp leading edges to cut rather than just puncture the skin.

The lancet body is preferably supported for linear displacement by the housing, in which case the operating means is conveniently disposed on the axis of displacement of the lancet body, at the opposite end to the piercing tip. Thus, advantageously, the lancet body, operating means and piercing tip form a generally elongate member. However, the lancet body may be non-linearly displaceable and/or the operating means may project from the housing to one-side of the lancet body. The operating means may be connected to the lancet body by a screw thread or other connection device such as a snap-engaging means which facilitates ready separation from the lancet body to disable the lancet device after use. However, preferably the operating means is integrally moulded with the lancet body and is breakable therefrom at a line of weakness at or adjacent the juncture with the housing when the lancet body is in its rest position.

15

Only a short application of pressure to the manual operating means is required in use of the lancet device, such that the pressure applied to the operating means is translated to the lancet body for displacing the lancet body from its rest position, so that when the device is held against a person's skin, the piercing tip is exposed long enough to cause an incision and produce an adequate amount of blood for testing. Once manual pressure is removed from the operating means, the lancet body is automatically retracted back to the rest position with the piercing tip within the housing due to the operation of the biasing means. The biasing means may hold the lancet body in its rest position. The biasing means can take any of many forms.

25

In one embodiment, the biasing means comprises at least one resilient projection or leaf spring in the housing which is deformed by the lancet body or operating means as the lancet body is displaced out of its rest position. Preferably, the or each resilient projection may be attached to the housing. Further preferably, the or each resilient projection is integral with the housing and, for example, may conveniently be moulded with the housing.

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Alternatively, the or each resilient projection or leaf spring, or other form of biasing means, may be integral with or attached to the lancet body, and is deformed by the housing as the lancet body is displaced out of its rest position.

5

In another embodiment, the biasing means may comprise a coil spring within the housing which is deformed by the lancet body or operating means as the lancet body is displaced out of its rest position.

- 10 One embodiment of a disposable lancet device in accordance with the present invention will now be described by way of example only with reference to the accompanying drawings in which:

15 Figure 1 is a front elevational view of the disposable lancet device, with the front removed for clarity;

Figure 2 is a sectional view along line AA of Figure 1, with the front cover in place and the lancet body removed; and

Figure 3 is a side view of the lancet body.

20

#### DETAILED DESCRIPTION OF THE DRAWINGS

The lancet device 10 shown in the Figures comprises a housing 12 and a lancet body 14. The housing 12 is preferably moulded in polypropylene and has a front wall 18 spaced 25 from a rear wall 16 by opposed side walls 20 and a top wall 22 extending between the side walls. The front wall 18 may be moulded separately to the remainder of the housing to facilitate the location of the lancet body 14 in the housing, or it may be integrally hinged to the remainder of the housing, for example along a join line (not shown) at the top wall 22. Either way, the front wall may be secured to the side walls 20 and top wall 22 by any 30 suitable means including bonding with a bonding agent, heat sealing, ultrasonic or other welding or snap-engaging or other connection devices.

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The housing 12 defines a passage 24 between the front and rear walls through which the lancet body 14 is manually displaceable. At one end of the passage, an opening 26 is provided in the top wall 22. At the other, the housing tapers to an opposed opening 28.

5 Above the tapered portion 30, the housing provides opposed planar gripping surfaces 32 on the front and rear walls, both of which may be used to hold the device 10 at least until the lancet body is actuated.

Within the housing a pair of opposed stop members 34 extend from the respective side 10 walls 20 towards each other to define a portion of the passage 24 therebetween. The stop members 34 are integrally moulded with the side walls and with the rear wall 16. Between the stop members 34 and the tapered portion 30 of the housing 12, a pair of opposed leaf springs 36 project towards each other from the side walls 20 to define another portion of the passage 24 therebetween. In contrast to the stop members 34, the leaf springs are 15 separate from both the front and rear walls 18 and 16 so that their distal end portions 38 can resiliently flex along the passage 24. The leaf springs 36 are conveniently integral with the side walls 20 and therefore preferably injection moulded in polypropylene, but they may be separately formed, for example, in stainless steel, and for example, located in slots (not shown) in the respective side walls.

20 The lancet body 14 has a shaft 40 and a pair of opposed rigid wing members 42 each sized to be received between the respective stop member 34 and leaf spring 36. At its proximal end 44, the lancet body 14 has a manual operating knob 46 connected to the lancet body by a weakened portion 48 formed, for example, of reduced diameter compared to the proximal 25 end 44 and knob 46. At its distal end 50 the lancet body 14 has a piercing tip 52 which may take any suitable form to provide a cutting point or blade. Preferably, as shown, the piercing tip is in the form of a narrow cutting edge 54.

30 Preferably, the lancet body 14 is also injection moulded in polypropylene, but if insufficient sharpness of the piercing tip 52 can be achieved with this material, it may instead be injection moulded in, for example, polystyrene or polycarbonate. Alternatively,

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instead of injection moulding the piercing tip 52 integrally with the remainder of the lancet body, it may be formed separately in the desired material and secured to the remainder of the lancet body.

- 5 The length of the shaft 40 and the relative position of the wing members 42 are such that with the wing members in the rest position between the stop members 34 and leaf springs 36 shown in Figure 1, the operating knob 46 projects from the housing 12 with the weakened portion 48 at the juncture with the housing, but the piercing tip 52 is concealed within the tapered portion 30 of the housing. Preferably, the operating knob 46 projects sufficiently from the top wall 22 that when it is manually pressed so as to be flush with the top wall the piercing tip 52 is exposed sufficiently to just pierce the skin of the finger 56 of the patient whose blood is being let when the finger 56 is engaged with the tapered end 28 of the housing 12.
- 10
- 15 In order to assemble the device 10, the operating knob 46 is passed outwardly through the opening 26 in the top wall 22 with the front wall 18 open or removed and the shaft 40 is disposed in the passage 24 with the members 42 between the respective stop members 34 and leaf springs 36. The front wall 18 is then secured to the side walls 20 and/or top wall 22, and the device is subjected to sterilisation.
- 20 As described above, in use, the operating knob 46 is displaced manually downwardly by pressure applied directly via the thumb or forefinger of the user to expose the piercing tip 52 and pierce the skin of the patient's finger 56. The manual displacement of the knob 46 and therefore of the shaft 40 causes the wing members 42 to resiliently deform the leaf springs 36 which then automatically retract the shaft and piercing tip 52 when the manual pressure is removed from the operating knob 46. When the lancet body 14 is returned to its rest position shown in Figure 1 by the leaf springs 36, the operating knob 46 is again exposed and may be broken off at the weakened portion 48 to prevent re-use.
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Those skilled in the art will appreciate that the invention described therein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention includes all such variations and modifications which fall within its spirit and scope.

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The reference to any prior art in this specification is not, and should not be taken as an acknowledgment or any form of suggestion that that prior art forms part of the common general knowledge in Australia.

- 10 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

15

CLAIMS

1. A disposable lancet device for piercing human skin comprising:
  - a lancet housing,
  - 5 a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body,
  - operating means engaged with the lancet body for manually displacing the lancet body to expose the piercing tip, and
  - biasing means against which the lancet body operates as it is manually displaced to
  - 10 expose the piercing tip whereby the biasing means automatically retracts the lancet body to its rest position when the manual displacement force is removed from the operating means,
  - wherein the operating means is adapted to be disengaged from the lancet body after
  - 15 use to prevent subsequent manual displacement of the lancet body from its rest position.
2. A disposable lancet device according to claim 1, wherein manual force applied to the operating means is translated to the lancet body for displacing the lancet body from its rest position.
- 20 3. A disposable lancet device according to claim 1, wherein the biasing means holds the lancet body in its rest position.
4. A disposable lancet device according to claim 1, wherein the biasing means comprises at least one resilient projection extending from the lancet body, wherein the resilient projection is deformed by a portion of the housing when the lancet body is displaced from its rest position.
- 25 5. A disposable lancet device according to claim 1, wherein the biasing means comprises at least one resilient projection extending from the housing, wherein the resilient projection is deformed by a portion of the lancet body when the lancet body is displaced

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from its rest position.

6. A disposable lancet device according to claim 1, wherein the biasing means comprises a coil spring.

5

7. A disposable lancet device according to claim 1, wherein the lancet body is supported for linear displacement by the housing.

8. A disposable lancet device according to claim 1, wherein the operating means is  
10 disposed on the axis of displacement of the lancet body.

9. A disposable lancet device according to claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

15 10. A disposable lancet device according to claim 1, wherein the lancet body is non-linearly displaceable.

11. A disposable lancet device according to claim 10, wherein the operating means projects from the housing to one side of the lancet body.

20

12. A disposable lancet device according to claim 1, wherein the operating means is integrally moulded with the lancet body.

13. A disposable lancet device according to claim 12, wherein the operating means is  
25 breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

14. A disposable lancet device according to claim 1, wherein the operating means is connected to the lancet body by a connection device.

30

15. A disposable lancet device according to claim 14, wherein the connection device is

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU00/00652

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int. Cl. : A61B 17/32		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Derwent: lancet dispos bias resil spring retract flex etc		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/10977 A (LIPSCHER) 27 April 1995 Pages 2-5,10, figures	1-3,7-9,11,16-18,20-23
X	WO 98/58584 A (OWEN MUMFORD LIMITED) 30 December 1998 Pages 1-5, figures	1-4,6-7,9,11,13-14,16-17,19-20
X	US 5630828 A (MAWHIRT et al) 20 May 1997 Columns 1-5, figures	1-3,7,9-12,14-20, 23
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p>		
Date of the actual completion of the international search 3 July 2000	Date of mailing of the international search report 12 JUL 2000	
Name and mailing address of the ISA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer  SUE THOMAS Telephone No : (02) 6283 2454	

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00652

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5643306 A (SCHRAGA) 1 July 1997 Pages 2-5, 7-10, figures	1-3, 7, 10-11, 14-17, 20-21, 13
X	US 5746761 A (TURCHIN) 5 May 1998 Columns 3-6, figures	1-3, 6-7, 9, 11, 16-17, 20, 23

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2301450	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. <b>PCT/AU00/00652</b>	International Filing Date ( <i>day/month/year</i> ) 9 June 2000	Priority Date ( <i>day/month/year</i> ) 10 June 1999	
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. 7 A61B 17/32</b>			
Applicant <b>N &amp; V CURIE PTY LTD et al</b>			

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.		
2.	This REPORT consists of a total of 3 sheets, including this cover sheet.  <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of 4 sheet(s).		
3.	This report contains indications relating to the following items:		
I	<input checked="" type="checkbox"/> Basis of the report		
II	<input type="checkbox"/> Priority		
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability		
IV	<input type="checkbox"/> Lack of unity of invention		
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
VI	<input type="checkbox"/> Certain documents cited		
VII	<input type="checkbox"/> Certain defects in the international application		
VIII	<input type="checkbox"/> Certain observations on the international application		

Date of submission of the demand 20 December 2000	Date of completion of the report 11 April 2001
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>SUE THOMAS</b> Telephone No. (02) 6283 2454

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00652

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed. the description,      pages 1, 3-7 , as originally filed,

pages , filed with the demand,

page 2, received on 3 April 2001 with the letter of 2 April 2001

 the claims,      pages , as originally filed,

pages , as amended (together with any statement) under Article 19,

pages , filed with the demand,

pages 8-10 , received on 3 April 2001 with the letter of 2 April 2001

 the drawings,      page 1/1, as originally filed,

pages , filed with the demand,

pages , received on with the letter of

 the sequence listing part of the description:

pages , as originally filed

pages , filed with the demand

pages , received on with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

 contained in the international application in written form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished4.  The amendments have resulted in the cancellation of: the description,      pages the claims,      Nos. the drawings,      sheets/fig.5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00652

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-23	YES
	Claims	NO
Inventive step (IS)	Claims 1-23	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-23	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The invention is a disposable lancet device for piercing human skin wherein the operating means is adapted to be disengaged from the lancet body after use to prevent subsequent displacement of the lancet body from its rest position.

The closest art,

WO 98/58584 provides a disposable lancet device for piercing human skin wherein the operating means is adapted to be disengaged from the lancet body to prevent subsequent displacement of the lancet body from its rest position but disengagement takes place during, and not after, use.

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

REC'D 19 APR 2001

WIPO

PCT

14

Applicant's or agent's file reference 2301450	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. <b>PCT/AU00/00652</b>	International Filing Date ( <i>day/month/year</i> ) 9 June 2000	Priority Date ( <i>day/month/year</i> ) 10 June 1999	
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. 7 A61B 17/32</b>			
<b>Applicant</b> N & V CURIE PTY LTD et al			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
 

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheet(s).

3. This report contains indications relating to the following items:

- I       Basis of the report
- II      Priority
- III     Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV     Lack of unity of invention
- V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI     Certain documents cited
- VII    Certain defects in the international application
- VIII    Certain observations on the international application

Date of submission of the demand 20 December 2000	Date of completion of the report 11 April 2001
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>SUE THOMAS</b> Telephone No. (02) 6283 2454

**I. Basis of the report****1. With regard to the elements of the international application:\***

the international application as originally filed.

the description, pages 1, 3-7, as originally filed,

pages , filed with the demand,

page 2, received on 3 April 2001 with the letter of 2 April 2001

the claims, pages , as originally filed,

pages , as amended (together with any statement) under Article 19,

pages , filed with the demand,

pages 8-10, received on 3 April 2001 with the letter of 2 April 2001

the drawings, page 1/1, as originally filed,

pages , filed with the demand,

pages , received on with the letter of

the sequence listing part of the description:

pages , as originally filed

pages , filed with the demand

pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:**

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4.  The amendments have resulted in the cancellation of:**

the description, pages

the claims, Nos.

the drawings, sheets/fig.

**5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00652

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-23	YES
	Claims	NO
Inventive step (IS)	Claims 1-23	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-23	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The invention is a disposable lancet device for piercing human skin wherein the operating means is adapted to be disengaged from the lancet body after use to prevent subsequent displacement of the lancet body from its rest position.

The closest art,

WO 98/58584 provides a disposable lancet device for piercing human skin wherein the operating means is adapted to be disengaged from the lancet body to prevent subsequent displacement of the lancet body from its rest position but disengagement takes place during, and not after, use.

- 2 -

involve complicated mechanisms which usually include a large number of components resulting in a device which is expensive to manufacture. Examples of proposed lancet devices of a complicated nature with a large number of components are given in US Patents 5,554,166, mentioned above, and 5,741,288.

5

According to the present invention there is provided a disposable lancet device for piercing human skin comprising:

a lancet housing,

10 a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body,

operating means engaged with the lancet body for manually displacing the lancet body to expose the piercing tip, and

15 biasing means against which the lancet body operates as it is manually displaced to expose the piercing tip whereby the biasing means automatically retracts the lancet body to its rest position when the manual displacement force is removed from the operating means,

wherein the operating means is adapted to be disengaged from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position.

The lancet device according to the present invention addresses the above problems in that 20 it can be used several times by a single user, either in the home or by a person administering the incision, so that a first attempt can be repeated if it does not succeed. The device can also be disabled permanently to prevent reuse and has a concealed tip to alleviate accidental piercing of the skin. The device may also have a relatively simple construction. In particular, it avoids the use of complicated spring-loaded mechanisms in 25 order to achieve successful incision of the skin.

The piercing tip is advantageously integral with the lancet body, and may be moulded with the lancet body in a plastics material such as polycarbonate, polystyrene or polypropylene. Polypropylene may not provide the tip with adequate piercing ability in which case 30 polystyrene is preferred. In this embodiment, the tip is preferably formed of metal such as stainless steel. The tip may have a cylindrical body tapering to a pointed end, but

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## CLAIMS

1. A disposable lancet device for piercing human skin comprising:  
a lancet housing,

5 a lancet body displaceably supported by the housing and having a piercing tip  
which is concealed within the housing in a rest position of the body,  
operating means engaged with the lancet body for manually displacing the lancet  
body to expose the piercing tip, and

10 biasing means against which the lancet body operates as it is manually displaced to  
expose the piercing tip whereby the biasing means automatically retracts the lancet  
body to its rest position when the manual displacement force is removed from the  
operating means,

15 wherein the operating means is adapted to be disengaged from the lancet body after  
use to prevent subsequent manual displacement of the lancet body from its rest  
position.

2. A disposable lancet device according to claim 1, wherein manual force applied to  
the operating means is translated to the lancet body for displacing the lancet body from its  
rest position.

20

3. A disposable lancet device according to claim 1, wherein the biasing means holds  
the lancet body in its rest position.

25 4. A disposable lancet device according to claim 1, wherein the biasing means  
comprises at least one resilient projection extending from the lancet body, wherein the  
resilient projection is deformed by a portion of the housing when the lancet body is  
displaced from its rest position.

30 5. A disposable lancet device according to claim 1, wherein the biasing means  
comprises at least one resilient projection extending from the housing, wherein the resilient  
projection is deformed by a portion of the lancet body when the lancet body is displaced

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from its rest position.

6. A disposable lancet device according to claim 1, wherein the biasing means comprises a coil spring.

5

7. A disposable lancet device according to claim 1, wherein the lancet body is supported for linear displacement by the housing.

8. A disposable lancet device according to claim 1, wherein the operating means is  
10 disposed on the axis of displacement of the lancet body.

9. A disposable lancet device according to claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

15 10. A disposable lancet device according to claim 1, wherein the lancet body is non-linearly displaceable.

11. A disposable lancet device according to claim 10, wherein the operating means projects from the housing to one side of the lancet body.

20

12. A disposable lancet device according to claim 1, wherein the operating means is integrally moulded with the lancet body.

25 13. A disposable lancet device according to claim 12, wherein the operating means is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

14. A disposable lancet device according to claim 1, wherein the operating means is connected to the lancet body by a connection device.

30

15. A disposable lancet device according to claim 14, wherein the connection device is

- 10 -

a snap engaging connection or screw thread.

16. A disposable lancet device according to claim 1, wherein the piercing tip is secured to the lancet body.

5

17. A disposable lancet device according to claim 1, wherein the piercing tip is integral with the lancet body.

18. A disposable lancet device according to claim 16, wherein the lancet body is 10 moulded around a mounting portion of the tip.

19. A disposable lancet device according to claim 1, wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene and polypropylene.

15

20. A disposable lancet device according to claim 18, wherein the piercing tip is formed of metal, preferably stainless steel.

21. A disposable lancet device according to claim 1, wherein the piercing tip has a 20 cylindrical body tapering to a pointed end.

22. A disposable lancet device according to claim 1, wherein the piercing tip is multi-sided.

25 23. A disposable lancet device according to claim 22, wherein the tip is pyramidal or flat with sharp leading edges.

REPLACED BY  
ART 34 AMDT

to prevent accidental cuts have also been proposed. However, these proposed devices involve complicated mechanisms which usually include a large number of components resulting in a device which is expensive to manufacture. Examples of proposed lancet devices of a complicated nature with a large number of components are given in US

- 5 Patents 5,554,166, mentioned above, and 5,741,288.

According to the present invention there is provided a disposable lancet device for piercing human skin comprising:

a lancet housing,

- 10 a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body,  
operating means for manually displacing the lancet body to expose the piercing tip, and  
biasing means against which the lancet body operates as it is manually displaced to expose  
the piercing tip whereby the biasing means automatically retracts the lancet body to its rest  
15 position when the manual displacement force is removed from the operating means,  
wherein disabling the operating means prevents manual displacement of the lancet body  
from its rest position.

- The lancet device according to the present invention addresses the above problems in that  
20 it can be used several times by a single user, either in the home or by a person  
administering the incision, so that a first attempt can be repeated if it does not succeed.  
The device can also be disabled permanently to prevent reuse and has a concealed tip to  
alleviate accidental piercing of the skin. The device may also have a relatively simple  
construction. In particular, it avoids the use of complicated spring-loaded mechanisms in  
25 order to achieve successful incision of the skin.

- The piercing tip is advantageously integral with the lancet body, and may be moulded with  
the lancet body in a plastics material such as polycarbonate, polystyrene or polypropylene.  
Polypropylene may not provide the tip with adequate piercing ability in which case  
30 polystyrene is preferred. In this embodiment, the tip is preferably formed of metal such as  
stainless steel. The tip may have a cylindrical body tapering to a pointed end, but

## CLAIMS

1. A disposable lancet device for piercing human skin comprising:
  - a lancet housing,
  - 5 a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body,
  - operating means for manually displacing the lancet body to expose the piercing tip, and
  - biasing means against which the lancet body operates as it is manually displaced to
  - 10 expose the piercing tip whereby the biasing means automatically retracts the lancet body to its rest position when the manual displacement force is removed from the operating means,
  - wherein disabling the operating means prevents manual displacement of the lancet body from its rest position.
- 15 2. A disposable lancet device according to claim 1, wherein manual force applied to the operating means is translated to the lancet body for displacing the lancet body from its rest position.
- 20 3. A disposable lancet device according to claim 1 or 2, wherein the biasing means holds the lancet body in its rest position.
4. A disposable lancet device according to any one of claims 1 to 3, wherein the biasing means comprises at least one resilient projection extending from the lancet body,
  - 25 wherein the resilient projection is deformed by a portion of the housing when the lancet body is displaced from its rest position.
5. A disposable lancet device according to any one of claims 1 to 3, wherein the biasing means comprises at least one resilient projection extending from the housing,
  - 30 wherein the resilient projection is deformed by a portion of the lancet body when the lancet body is displaced from its rest position.

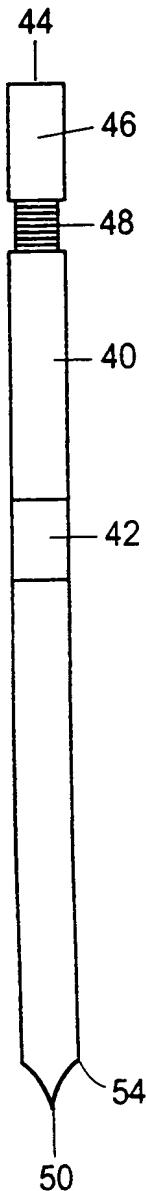
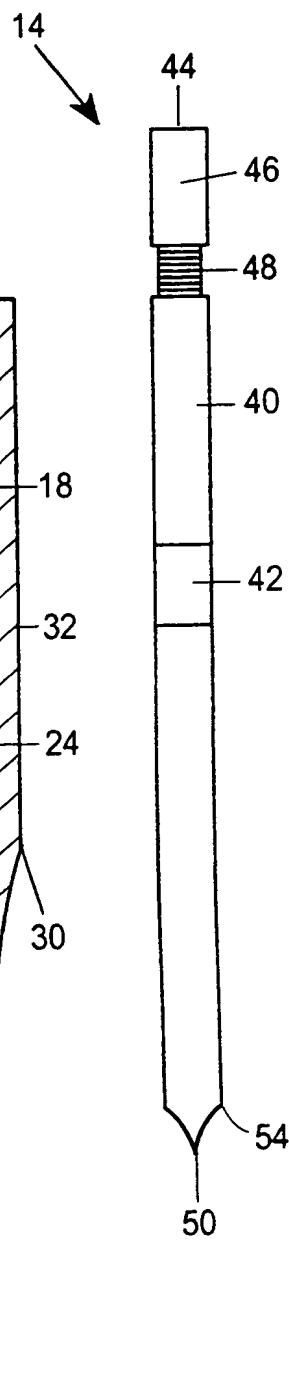
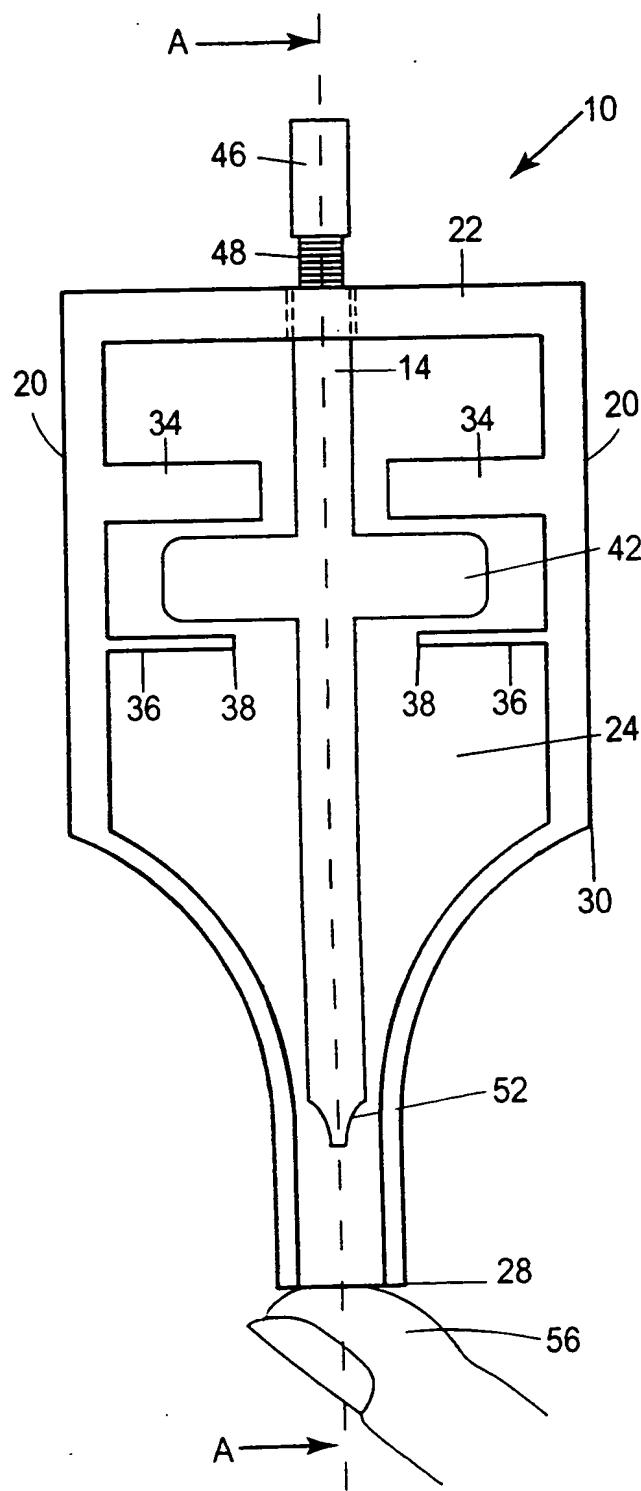
- 9 -

6. A disposable lancet device according to any one of claims 1 to 3, wherein the biasing means comprises a coil spring.
7. A disposable lancet device according to any one of the preceding claims, wherein  
5 the lancet body is supported for linear displacement by the housing.
8. A disposable lancet device according to any one of the preceding claims, wherein the operating means is disposed on the axis of displacement of the lancet body.
- 10 9. A disposable lancet device according to any one of the preceding claims, wherein the lancet body, operating means and piercing tip form a generally elongate member.
10. A disposable lancet device according to any one of claims 1 to 6, wherein the lancet body is non-linearly displaceable.
- 15 11. A disposable lancet device according to claim 10, wherein the operating means projects from the housing to one side of the lancet body.
12. A disposable lancet device according to any one of the preceding claims, wherein  
20 the operating means is integrally moulded with the lancet body.
13. A disposable lancet device according to claim 12, wherein the operating means is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.
- 25 14. A disposable lancet device according to any one of claims 1 to 11, wherein the operating means is connected to the lancet body by a connection device.
15. A disposable lancet device according to claim 14, wherein the connection device is  
30 a snap engaging means or screw thread.

- 10 -

16. A disposable lancet device according to any one of the preceding claims, wherein the piercing tip is secured to the lancet body.
17. A disposable lancet device according to any one of claims 1 to 15, wherein the  
5 piercing tip is integral with the lancet body.
18. A disposable lancet device according to claim 16, wherein the lancet body is moulded around a mounting portion of the tip.
- 10 19. A disposable lancet device according to any one of the preceding claims, wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene and polypropylene.
- 15 20. A disposable lancet device according to claim 18, wherein the piercing tip is formed of metal, preferably stainless steel.
21. A disposable lancet device according to any one of the preceding claims, wherein the piercing tip has a cylindrical body tapering to a pointed end.
- 20 22. A disposable lancet device according to any one of claims 1 to 20, wherein the piercing tip is multi-sided.
23. A disposable lancet device according to claim 22, wherein the tip is pyramidal or flat with sharp leading edges.

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FIG 1FIG 2FIG 3

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00652

**A. CLASSIFICATION OF SUBJECT MATTER**

Int. Cl. ? A61B 17/32

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Derwent: lancet dispos bias resil spring retract flex etc**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95/10977 A (LIPSCHER) 27 April 1995 Pages 2-5,10, figures	1-3,7-9,11,16-18,20-23
X	WO 98/58584 A (OWEN MUMFORD LIMITED) 30 December 1998 Pages 1-5, figures	1-4,6-7,9,11,13-14,16-17,19-20
X	US 5630828 A (MAWHIRT et al) 20 May 1997 Columns 1-5, figures	1-3,7,9-12,14-20, 23

Further documents are listed in the continuation of Box C     See patent family annex

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search  
3 July 2000Date of mailing of the international search report  
12 JUL 2000Name and mailing address of the ISA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail address: pct@ipaaustralia.gov.au  
Facsimile No. (02) 6285 3929Authorized officer  
**SUE THOMAS**  
Telephone No : (02) 6283 2454

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00652

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5643306 A (SCHRAGA) 1 July 1997 Pages 2-5, 7-10, figures	1-3, 7, 10-11, 14-17, 20-21, 13
X	US 5746761 A (TURCHIN) 5 May 1998 Columns 3-6, figures	1-3, 6-7, 9, 11, 16-17, 20, 23

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
**PCT/AU00/00652**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9510977	AU	80824/94	HU	3783	US	5624458
WO	9858584	AU	81149/98	EP	925022		
US	5630828	WO	9738636				
US	5643306	CA	2200502	EP	796592		
US	5746761	NONE	CA 5643306	2200502	EP	796592	US

END OF ANNEX

# PATENT COOPERATION TREATY

MONDAY 8 JAN 2001

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

**PCT**

To: Agent :

DAVIES COLLISON CAVE  
1 Little Collins Street  
MELBOURNE VIC 3000

## NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 59.3(e) and 61.1(b), first sentence  
and Administrative Instructions, Section 601(a))

Date of mailing (day/month/year)	5 JAN 2001 (5/1/01)
-------------------------------------	------------------------

Applicant's or agent's file reference  
2301450

### IMPORTANT NOTIFICATION

International application No.  
PCT/AU00/00652

International filing date (day/month/year)  
9 JUN 2000 (9/6/00)

Priority date (day/month/year)  
10 JUN 1999 (10/6/99)

Applicant

N & V Curie Pty Ltd (et al.)

- The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

20 DEC 2000 (20/12/00)

- That date of receipt is:

- the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
- the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
- the date on which this Authority has, in response to the Invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

- Attention:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide, Volume II*.

- (*If applicable*) This notification confirms the information given by telephone, facsimile transmission or in person on:

- Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/AU  
**AUSTRALIAN PATENT OFFICE**  
**PO BOX 200, WODEN ACT 2606, AUSTRALIA**  
E-mail: pct@ipaaustralia.gov.au  
Facsimile No. 02 6285 3929

Authorized officer

**JOSEPH BRESIC**  
**02 6283 2357**

Telephone No.

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ \_\_\_\_\_

# PCT

## CHAPTER II

### DEMAND

under Article 31 of the Patent Cooperation Treaty:

The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA		Date of receipt of DEMAND
<b>Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION</b>		Applicant's or agent's file reference 2301450/PHH
International application No. PCT/AU00/00652	International filing date (day/month/year) 9 June 2000 09.06.2000	(Earliest) Priority date (day/month/year) 10 June 1999 10.06.1999
Title of invention DISPOSABLE LANCET DEVICE		
<b>Box No. II APPLICANT(S)</b>		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)  N & V CURIE PTY LTD 32 Cliff Road Frankston Victoria 3199 AUSTRALIA	Telephone No.: -	
	Facsimile No.: -	
	Teleprinter No.: -	
State (that is, country) of nationality: AUSTRALIA	State (that is, country) of residence: AUSTRALIA	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)  CURIE, Napolean 32 Cliff Road Frankston Victoria 3199 AUSTRALIA		
State (that is, country) of nationality: AUSTRALIA	State (that is, country) of residence: AUSTRALIA	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)  		
State (that is, country) of nationality:	State (that is, country) of residence:	
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.		

**Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**

The following person is  agent  common representative

and  has been appointed earlier and represents the applicant(s) also for international preliminary examination.

is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: (*Family name followed by given name; for a legal entity, full official designation.  
The address must include postal code and name of country.*)

HUNTSMAN, Peter      DAVIES COLLISON CAVE  
SLATTERY, John      1 Little Collins Street  
DARK, Andrew      Melbourne Victoria 3000  
                          AUSTRALIA

Telephone No.:  
+61-3-9254 2777

Facsimile No.:  
+61-3-9254 2770

Teleprinter No.:  
-

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION****Statement concerning amendments:\***

1. The applicant wishes the international preliminary examination to start on the basis of:

the international application as originally filed  
the description  as originally filed  
 as amended under Article 34

the claims  as originally filed  
 as amended under Article 19 (together with any accompanying statement)  
 as amended under Article 34

the drawings  as originally filed  
 as amended under Article 34

2.  The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3.  The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). (*This check-box may be marked only where the time limit under Article 19 has not yet expired.*)

- \* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: .....ENGLISH.....

- which is the language in which the international application was filed.  
 which is the language of a translation furnished for the purposes of international search.  
 which is the language of publication of the international application.  
 which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

**Box No. V ELECTION OF STATES**

The applicant hereby elects all eligible States (*that is, all States which have been designated and which are bound by Chapter II of the PCT*)

excluding the following States which the applicant wishes not to elect:

**Box No. VI CHECK LIST**

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- |  |   |        |                          |                          |
|--|---|--------|--------------------------|--------------------------|
| 1. translation of international application                              | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. amendments under Article 34   | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. copy (or, where required, translation) of statement under Article 19  | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. letter  | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. other (specify)   | : | sheets | <input type="checkbox"/> | <input type="checkbox"/> |

For International Preliminary Examining Authority use only

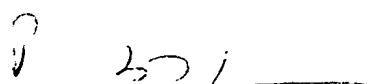
received      not received

The demand is also accompanied by the item(s) marked below:

- |  |   |
|--|---|
| 1. <input type="checkbox"/> fee calculation sheet  | 4. <input type="checkbox"/> statement explaining lack of signature                                  |
| 2. <input type="checkbox"/> separate signed power of attorney                            | 5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form |
| 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input type="checkbox"/> other (specify):  |

**Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

  
PETER HUNTSMAN  
 (For and on behalf of the Applicants)

## For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3.  The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.  The applicant has been informed accordingly.
4.  The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5.  Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

## For International Bureau use only

Demand received from IPEA on: